



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

In the Matter of)
)
International Cyclotron, Inc.) Docket Nos. 030-37882 & 030-37957
Hato Rey, Puerto Rico) License Nos. 052- 31352-01MD/52-31352-02
) EA-11-086

ORDER SUSPENDING LICENSED ACTIVITIES

[NRC-2011-0292]

I

International Cyclotron, Inc. (International Cyclotron; Licensee) is the holder of Byproduct Materials License Nos. 52-31352-01MD and 52-31352-02, issued on August 20, 2009, by the U.S. Nuclear Regulatory Commission (NRC or the Commission) pursuant to Title 10 of the *Code of Federal Regulations* (CFR) Part 30. License No. 52-31352-01MD authorizes the preparation and distribution of radioactive drugs and radiochemicals for medical and non-medical use and the possession and storage of byproduct materials incidental to radionuclide production. License No. 52-31352-02 authorizes the use of an accelerator to produce pharmaceutical radionuclides, the packaging and distribution of produced radiochemicals and sealed sources, possession and storage of byproduct materials incidental to radionuclide production, and calibration and checking of the licensee's instruments. The licenses are scheduled to expire on August 31, 2019.

II

NRC regulations specified in 10 CFR 30.35 require that applicants for authorization to

possess and use byproduct radioactive material above specified amounts must provide a guarantee or other financial arrangement that funds for decommissioning will be available when needed (i.e., financial assurance). The requirement to provide financial assurance is in addition to the licensee's regulatory obligation to decommission its facilities, and is to ensure that a suitable mechanism for financing the decommissioning of licensed facilities is in place in the event that a licensee is unable or unwilling to complete decommissioning.

When International Cyclotron submitted its NRC license application related to the cyclotron, it requested authorization to possess and use radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to Part 30. NRC regulations at 10 CFR 30.35(a)(1), require International Cyclotron to submit a Decommissioning Funding Plan (DFP) which, as described in 10 CFR 30.35(e), must consist of:

1. a cost estimate for decommissioning;
2. a description of the method for assuring funds for decommissioning;
3. a description of the means for adjusting cost estimates and associated funding levels periodically over the life of the facility;
4. a certification that financial assurance for decommissioning has been provided in the amount of the cost estimate; and,
5. a signed original of the financial assurance instrument, which meets the regulatory requirements of 10 CFR 30.35(f).

International Cyclotron failed to submit the required DFP with its application. The NRC addressed this deficiency after issuing International Cyclotron the NRC license; in a letter dated December 7, 2009, notified International Cyclotron of its requirement to provide financial assurance, advised International Cyclotron was in non-compliance with 10 CFR 30.35, and requested that International Cyclotron come into compliance with NRC regulations and submit the necessary supporting documentation.

Between December 7, 2009, and October 12, 2011, the NRC contacted International Cyclotron on multiple occasions through letters, telephone calls, and electronic mail explaining the regulatory requirements for providing financial assurance. International Cyclotron has not provided NRC with information that demonstrates International Cyclotron has established financial assurance, as required by NRC regulations at 10 CFR 30.35.

By letter dated September 2, 2011 (ML112450249), the NRC issued a Request for Additional Information (RAI) to International Cyclotron, which identified significant deficiencies in your draft decommissioning cost estimate and stated that “you must re-submit your DFP and cost estimate in full, with all tables and any additional pages to provide sufficient description of the bases for your work and cost estimates.” Additionally, the RAI advised International Cyclotron that the certification of financial assurance (CFA) is not accepted because: a) it is not an original, signed document by a management representative; and b) the CFA states that financial assurance in the amount of \$1,125,000 has been obtained. Confirm that you will submit a revised CFA, and that it will be an original document with a signature from a management representative, in accordance with Appendix A.2.2, A.2.3, A.2.4 and A.2.5 of NUREG-1757, Vol.3; and that it will reflect the amount of decommissioning funding you are actually providing (at a minimum, the funding required will be the amount of the cost estimate as accepted by the NRC). The RAI letter required that International Cyclotron respond to the NRC within 30 days and stated that enforcement action would be initiated against International Cyclotron, if financial assurance requirements were not established.

International Cyclotron failed to respond within 30 days. On October 14, 2011, International Cyclotron submitted a late response containing a signed cost estimate for decommissioning with a description of the method for assuring funds for decommissioning and the means for periodically adjusting the cost estimate (items 1, 2, and 3 as noted above). The

NRC reviewed those documents and found them to be acceptable. On October 24, 2011, International Cyclotron submitted another response containing a signed certification statement (item 4 from above). The October 24, 2011 response, however, was incomplete and International Cyclotron remains in non-compliance because a financial assurance instrument fulfilling the requirements of 10 CFR 30.35(f) was not provided; International Cyclotron has not submitted the financial assurance instrument (item 5 from above) as of December 19, 2011.

III

Based on the above factors, it appears that International Cyclotron has failed to meet the NRC requirements pertaining to financial assurance for decommissioning, contrary to 10 CFR 30.35. The NRC must be able to rely upon licensees to comply with NRC requirements. International Cyclotron's failure to obtain and submit a financial assurance instrument in the amount of the cost estimate has prevented the NRC from ensuring that funds will be available at the time of shutdown to provide for orderly and timely decommissioning to protect public health and the environment.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED THAT:

1. The authority to prepare and distribute radioactive drugs and radiochemicals under License No. 52-31352-01MD and to produce or handle radiochemicals and sealed

sources, and package and distribute produced radiochemicals and sealed sources under License No. 52-31352-02 will be suspended, effective 60 days from the date of this Order, if the Licensee does not, within this 60-day period, provide a financial assurance instrument for decommissioning which the NRC determines is acceptable. The only activities that are not suspended are possession and storage of byproduct materials, and calibration and checking of the Licensee's instruments.

2. From the date of suspension, until notified by the Commission in writing that a financial assurance instrument has been accepted; the Licensee shall restrict all activities except possession and storage of byproduct materials, and calibration and checking of the Licensee's instruments.
3. The Licensee shall not receive any additional NRC-licensed material while the suspension is in effect.

The Director, OE, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

V

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order within 60 days of service of this Order. In addition, the Licensee and any other person adversely affected by this Order may request a hearing on this Order within 60 days of its publication in the Federal Register. Where good cause is shown, consideration will be given to extending the time to answer or request a

hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings, unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>. System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site->

[help/e-submittals.html](http://www.nrc.gov/site-help/e-submittals.html). Participants may attempt to use other software not listed on the web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, web-based submission form. In order to serve documents through EIE, users will be required to install a web browser plug-in from the NRC web site. Further information on the web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail at MSHD.Resource@nrc.gov, or by a toll-free call at (866) 672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket, which is available to the public at http://ehd.nrc.gov/EHD_Proceeding/home.asp, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d).

If a hearing is requested by a licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Roy P. Zimmerman, Director
Office of Enforcement

Dated this 19th day of December 2011

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